

### **DETAILED ACTION**

Claims 1-5, 7, 9-11, 14-16 and 19 directed to an allowable product. Pursuant to the procedures set forth in MPEP § 821.04(B), claims 20-23, directed to the process of making or using an allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104.

Because all claims previously withdrawn from consideration under 37 CFR 1.142 have been rejoined, **the restriction requirement as set forth in the Office action mailed on 1/28/08 is hereby withdrawn.** In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

### **EXAMINER'S AMENDMENT**

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Ms. Kay Chang on 10/1/09.

The application has been amended as follows:

Please cancel claims **17** and **18**.

Please replace claim **1** with the following.

1. (Currently Amended) An orally administrable composition containing particles with a particle size of 500 nm or less, comprising:

0.1 to 30 weight% of a complex of a charged water-soluble drug and a counter-ion substance in which the charged water-soluble drug is ionically bonded with the counter-ion substance, wherein said counter-ion substance is an anionic compound selected from the group consisting of sodium salt of C<sub>8-18</sub> fatty acid, sodium salt of bile acid, sodium alginate, and sodium carboxymethylcellulose, or a cationic compound selected from the group consisting of carnitine salt, benzalkonium chloride, cetrimide, and mixtures thereof;

0.5 to 80 weight% of a lipid, wherein said lipid is an aliphatic alcohol selected from the group consisting of monoglyceride, diglyceride, propyleneglycol fatty acid ester, glycerol fatty acid ester, cetostearyl alcohol, cetyl alcohol, and mixtures thereof;

0.5 to 80 weight% of a polymer, wherein said polymer is selected from the group consisting of methacrylic acid copolymer, hydroxypropyl methylcellulose phthalate, hydroxypropyl methylcellulose acetate succinate, cellulose acetate phthalate, shellac, chitosan, hydroxypropyl methylcellulose and its derivative, ethylcellulose, methylcellulose, polyvinylalcohol, sodium alginate, carbomer, and mixtures thereof;

0.1 to 30 weight% of a cryoprotective agent, wherein the cryoprotective agent is selected from the group consisting of glucose, mannitol, sorbitol, trehalose, amino acid, albumin, and mixtures thereof; and

1 to 80 weight% of an emulsifier,

wherein the weight ratio of said lipid and said polymer is in the range of 1:0.05 to 3 and said complex is entrapped in said lipid and said polymer is inserted between said lipid.

***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Satyanarayana R. Gudibande whose telephone number is 571-272-8146. The examiner can normally be reached on M-F 8-4.30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Satyanarayana R Gudibande/  
Examiner, Art Unit 1654

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Primary Examiner, Art Unit 1654